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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,782	09/11/2003	Liat Mintz	28238	6045

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/659,782	
Examiner	MINTZ, LIAT	
Jennifer Dunston	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 25-46 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) ____ is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claim(s) 25-46 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Claims 25-46 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 25-30 and 35-37, drawn to an isolated nucleic acid sequence, an expression vector comprising the isolated nucleic acid sequence, a host cell transfected with the expression vector, a primer, and a probe, classified in class 536, subclass 23.1.
- II. Claims 31-34, drawn to an amino acid sequence, classified in class 530, subclass 350.
- III. Claims 38-43 and 46, drawn to a method for detecting or determining the level of a variant nucleic acid sequence in a biological sample, classified in class 435, subclass 6.
- IV. Claim 44, drawn to a method for identification of compounds capable of affecting the binding affinity of a protein to a receptor, classified in class 435, subclass 4.
- V. Claim 45, drawn to a method for determining the ratio between the level of an obesity and/or diabetes related protein variant in a first biological sample and a variant produced by alternative splicing in a second biological sample, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Group I, and the polypeptides of Group II are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

The inventions of Groups III-V are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups III-V comprise steps which are not required for or present in the methods of the other groups: detecting a hybridization complex (Group III), determining the effect of the candidate compound on the binding of the amino acid sequence to the at least one receptor (Group IV), and determining the level of a first amino acid sequence of an obesity and/or diabetes related gene variant in a first biological sample (Group V). The end results of the methods are different: detecting the presence of at least one variant nucleic acid sequence (Group III), identifying compounds capable of affecting the binding affinity of obesity and/or diabetes related proteins to the receptors of said proteins (Group IV), and determining the ratio between the level of an obesity and/or diabetes related protein variant in a first biological sample and a variant produced by alternative splicing in a second biological sample (Group V). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used in a materially different process such as overexpressing the protein in a cell line.

Inventions of Group II and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the amino acid sequence of Group II can be used in a materially different process such as the production of antibodies specific to the protein.

Except for the specific relationships described above, the inventions of Groups I-II and Groups III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I-II are not necessarily used in or made by the methods of Groups III-V.

Claims 25, 32, 37-39, 44 and 46 are claimed in a Markush type format. However, the members of the groups do not possess unity of invention and instead are patentably distinct inventions recited in the alternative. The members of the group are different and patentably distinct from each other because each member is a different nucleic acid or protein with distinct chemical structure and biological function. Each nucleic acid is an alternatively spliced variant of a known transcript. Although some of the nucleic acid sequences are variants of the same known transcript, each variant constitutes unique chemical structure with a different biological

function in that they code for different proteins. Further, the amino acid sequences of the translated splice variants are each chemically distinct structures with potentially different biological functions. Thus, there is no structural/functional relationship between the members of the group (See MPEP § 803.02). Upon election of any group that contains any of the aforementioned nucleic acids or proteins, Applicant is required to elect one of the members of the group set forth in the claim(s). This is NOT an election of species, but rather an election of a distinct invention, owing to the functional differences between the members of the Markush-like group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Furthermore, searching any of the inventions of Groups I-V together would impose a serious search burden. The distinct steps and products require separate and distinct searches of the non-patent literature. Further, Groups I-IV require a sequence search of the commercial database, and each amino acid sequence and nucleic acid sequence requires a separate search.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are

governed by 37 C.F.R. § 1.116; amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with the 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad



TERRY MCKELVEY
PRIMARY EXAMINER